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SECTION K

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Submitter Information

AOC Medical Systems
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2. Model AOC Phase II 25 Surgical Diode Laser

3. Predicate or Legally Marketed Devices:

<u>Manufacturer</u>	<u>Model</u>	<u>Laser Type</u>
AOC Medical Sys.	AOC 25	980 nm Diode Laser
Cynosure	Phototome	980 nm Diode Laser
Cytocare	DioLase HP-1	980 nm Diode Laser
DioMed	DioMed 25	810 nm Diode Laser
Indigo Medical	IDE 830E	830 nm Diode Laser
Sharplan Lasers	6020	810 nm Diode Laser

4. General System Description

The AOC Medical Systems Model Phase II 25 Fiber-Coupled Diode Laser System delivers up to 25 watts of CW optical power from a compact, air cooled unit. It is a complete, self-contained instrument, including a high efficiency power supply, an adjustable light output with constant current operation and a visible aiming laser. The system couples the laser light into high numerical aperture delivery fibers fitted with standard SMA-905 fiber connectors.

The diode lasers in this unit were fabricated by Applied Optronics Corp. from single quantum well, strained-layer, indium gallium aluminum on gallium arsenide semiconductor material. The diode lasers are sealed in

a rugged, factory-aligned, environmentally protective module. High electrical efficiency of the diode lasers eliminate the need for water cooling and assure low maintenance, reliable laser operation for this all-solid-state system. Each individual diode laser emits at a narrow wavelength; however coupling several diodes through a fiber optic bundle results in each diode wavelength contributing to a broader spectrum emitted from the final delivery fiber. The laser energy is centered at 980nm with a total range from approximately 970-1000nm.

The AOC Phase II 25 has a modular design comprised of:

- Laser Diode and Cooling Module containing the laser diodes, the heat sink and fans.

- Optics Module containing a beamsplitter pick-off for display of the total optical power.

- Front panel for simple control of the unit.

- Transformer isolated power supplies and control electronics.

Unique attributes of this system include the following:

- Multiple, individually fiber-coupled, high power diode lasers mounted on a large thermal footprint to allow sustained high power CW operation *without* water cooling.

- Optical power level continuously adjustable from the front panel, with display of optical output power.

- Low power, visible aiming laser for beam targeting prior to activation of the high power lasers. The aiming laser is controlled independently of the high power lasers.

- Immediate turn-on capability. No warm-up period. No system alignments or maintenance to be made by the user.

- Forced air cooling (no water). Maximum inlet air temperature 30° C.

- Individually replaceable, fiber pigtailed diode lasers. Repairs performed at factory.

The microprocessor controlled AOC Phase II 25 diode laser system is designed to allow easy and safe operation of the laser using controls common to other surgical laser systems. The laser system utilizes a menu driven set-up operation for user prompts and program entry. The laser can be set for continuous output or programmed for single or repeat pulses at output powers up to 25 watts. A footswitch or handswitch, activated by the user, always controls laser output. An optional remote control for use in a sterile plastic dressing (e.g., standard OR microscope drape) allows the user to change the power and activate Ready and Standby Modes.

The following pre-packaged, presterilized disposable optical fibers are available for use with the AOC Phase II 25 laser system:

<u>Fiber Model</u>	<u>Type</u>
AOC DCLF-600	600µm Conical tip
AOC DCLF-1000	1000µm Conical tip
AOC DCLF-600B	600µm Hemispherical Ball tip
AOC DCLF-1000B	1000µm Hemispherical Ball tip
AOC DBLF-60S	600µm Side firing
AOC DBLF-100S	1000µm Side firing
AOC DBLF-60SF	600µm Scatter Free Side firing
AOC DBLF-60	600µm Free Beam
AOC Neos	Conical (conical shaped)
AOC Neos	Delta (wedge shaped) Handpiece, Laparoscopic and Bare Fiber
AOC HSD	Conical shaped with electrode

5. Intended Use:

The AOC Phase II 25 surgical diode laser system has the same general intended use as the predicate diode lasers. This intended use includes incision, excision, coagulation and vaporization applications in the following surgical specialties:

Urology
Gynecology
Gastroenterology
Pulmonology
General and Thoracic Surgery
Neurosurgery (hemostasis)
Ear, Nose, and Throat; Head/Neck Surgery
Dermatology/Plastic Surgery

No new intended use was sought in this Premarket Notification.

The wavelength (980 nm) and tissue effects of the AOC Phase II 25 diode laser are closely matched to the predicate lasers at 805-830 and 980 nm. The 980 nm wavelength absorption in tissue is less dependent on variations in tissue pigment or vascularity than at 805 nm and has a slightly higher water absorption than the 1064 nm wavelength. Other predicate 980 nm diode laser systems have been found substantially equivalent to Nd:YAG and 805 nm diode lasers.

6. Comparison of Technological Characteristics

The AOC Phase II 25 laser output is at the same nominal wavelength, 980 nanometers as the AOC 25, Cynosure Phototome, and Cytocare DioLase HP-1 lasers. Its laser tissue interactions would be expected to be identical. The same individual diode laser components are supplied by Applied Optronics for all four laser systems. The AOC Phase II 25 differs in wavelength from the DioMed 25, Indigo 830 and Sharplan 6020 (at 805 -830 nanometers) which has a slightly greater energy absorption in pigment and blood rich tissue. The 980 nm wavelength, like the Nd:YAG wavelength at 1064 nm, is less dependent on variations in tissue pigment and blood content.

The temporal output of all these systems is the same. These lasers are operated most often in the Continuous Wave (steady state) Mode but can be electronically gated to produce time pulses, single or repeated. The AOC Phase II 25 laser has a Continuous, Single Pulse, Countdown Pulse, Repeat Pulse, and Exponential Pulse output which are found on one or more of the predicate lasers. Its range of timed outputs are within the ranges of the above cleared products.

The output power of the AOC Phase II 25 is about the same as the power of the Diomed 25, Indigo 830, and Sharplan 6020. For applications using contact fibers with sculpted tips which typically operate below 25 watts, the difference in output is not clinically significant. The lower output power of the AOC Phase II 25 in comparison to the CytoCare and Cynosure 980 nm lasers can be compensated for by using smaller diameter fibers for equal power density or exposing target tissue for longer duration (equivalent energy).

The AOC Phase II 25 laser system has the same overall characteristics and features as the predicate diode laser systems. Like these lasers, the AOC Phase II 25 provides for adjustable power output, internal monitoring of power output accuracy, prominent power output display, operation in the Continuous Mode and Single Pulse, and other Modes (with adjustable pulse duration), foot switch activation, safety interlocks, a red aiming beam, Ready and Standby Modes, an electrically safe design, visual and audible indicators of operation, as well as a rugged cabinet designed for the clinical environment.

Like The Sharplan 6020, the AOC Phase II 25 is equipped for handswitch activation of the laser output for convenient surgical control. Also, like the Indigo unit, the AOC Phase II 25 has a Decay (e.g., exponential) Pulse mode.

7. Performance Data

No clinical test data was submitted in support of this submission. Peer reviewed clinical articles on the tissue interaction at 980 nm were included in the 510 (k). Bench test data was submitted demonstrating that the design is able to produce the rated power and wavelength.

Notice: This Summary was prepared in order to comply with CFR 21 807.87. AOC Medical Systems makes no claim that any disease or other condition can be cured and promotes its laser as a surgical tool only for use by qualified physicians. Laser surgery, like any surgery, entails necessary risks, some of which may result in complications, injury or, in the extreme, death.